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Docket No. MCP 262

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SEP 22 2003
9/11/03
C. Evans

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Bunick & Luber
Serial No. : 09/752,899 Art Unit : 1615
Filed : December 29, 2000 Examiner : C. Evans
Title : Soft Tablet Containing Dextrose Monohydrate

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Sharon E. Hayner
(Name of applicant, assignee, or Registered Representative)

JH
(Signature)

9/11/03
(Date of Signature)

Honorable Commissioner of Patents
Washington, D.C. 20231

RESPONSE

Dear Sir:

This paper is in response to the Office Action mailed June 12, 2003.

This application, as amended, contains claims 1-5 and 7-13. Claims 1 and 12 are independent. Claim 1 recites a tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing, comprising a pharmaceutically active ingredient and a matrix comprising directly compressible dextrose monohydrate and about 0.005 to about 10 % by weight of sucralose. The tablet contains less than 5% by weight of fat and said matrix is substantially free of non-saccharide, water-soluble polymeric binders.

Claim 12 also recites a tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing, comprising a pharmaceutically active ingredient and a matrix comprising directly compressible dextrose monohydrate and about 0.005 to about 10 % by weight of sucralose. The matrix also comprises at least one disintegrating agent selected from microcrystalline cellulose, starch, sodium starch glycolate, crosslinked

polyvinylpyrrolidone, crosslinked carboxymethylcellulose, and mixtures thereof; at least one lubricant selected from magnesium stearate, stearic acid, and mixtures thereof; and optionally an auxiliary ingredient selected from fillers, sweeteners, surfactants, glidants, acidulents, antioxidants, preservatives, coloring, flavoring agents, and mixtures thereof. The tablet is substantially free of triglycerides and said matrix is substantially free of non-saccharide, water-soluble polymeric binders.

The Examiner has rejected all of the pending claims under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 4,684,534 to Valentine in view of U.S. Patent No. 4,327,076 to Puglia. The Examiner argues that Valentine teaches a chewable tablet comprising active ingredients, dextrose monohydrate and sucrose, according to the Examiner an obvious variant of sucralose. Puglia was cited for a teaching of a compressed tablet containing fats in the range of 2 to about 45%. The Examiner maintained that applicants' recitation of amounts of fat and water-soluble polymeric binder were obvious, optimum ranges.

Applicants respectfully request reconsideration of this rejection. As previously explained, the Valentine tablet comprises an active ingredient and an agglomerate. The agglomerate in turn comprises a carbohydrate such as dextrose monohydrate or sucrose held together by water-soluble binder that also may be sucrose. It is assumed that the Examiner is viewing sucrose in the role of a water-soluble binder, the amount of which, according to Valentine, should be in the range of from about 1 percent to about 10 percent by weight of the agglomerate.¹

There are important differences between Valentine and the claimed invention. First, the claimed invention requires the use of directly compressible dextrose monohydrate. It is well known by those skilled in the art that this a particulate form of dextrose monohydrate that has not been granulated. Applicants' specification states:

The dextrose monohydrate is present in the tablet in directly compressible form. That is, the dextrose monohydrate has an average particle size of about 100 to about 500 microns, preferably about 100 to about 250 microns, more preferably about 150 to about 200 microns. Such a particle size is required to impart the

¹ As explained in applicants' Amendment mailed April 15, 2003, if sucrose is used as the carbohydrate in the Valentine formulation, the amount necessary under Valentine would completely different from that appropriate for applicants' invention.

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formulation with adequate flowability and compressibility, and with a smooth and creamy mouthfeel according to the invention.

Page 3, line 30 to page 4, line 3. In contrast, Valentine granulates his carbohydrate (dextrose monohydrate) with the water-soluble binder. See column 3, lines 53 to column 4, line 13. This forms the carbohydrate-based agglomerate that is the crux of Valentine's formulation.

Second, if the role of sucrose in Valentine is as a binder, this is completely different than the role of sucralose in the claimed invention, which is as a sweetener. The Examiner has provided no evidence whatsoever that sucrose and sucralose are interchangeable as binder materials, or that sucralose is even useable as a binder material. The Examiner has cited WO 99/47126 of Lui, but this reference only suggests that the two are sweeteners.

Accordingly, neither the carbohydrate nor the sucrose used by Valentine are comparable to the dextrose monohydrate and sucralose of the claimed invention. Puglia, the secondary reference, does not remedy these defects.

For these reasons, the claimed invention is patentable. Reconsideration of the application is therefore requested.

Respectfully submitted,

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Dated: 9/11/03